DETAILED ACTION

Response to Amendment

1. The amendment filed 12/29/09 has been entered.

2. The rejection of claims 8-10, 14, 22 & 25 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is withdrawn due to the amendment of the claims to use of an ANP or BNP compound, and because SEQ ID NOs: 1-8 describe various natriuretic peptides from different species.

3. Applicant's arguments filed 12/29/09 have been fully considered but they are not deemed to be persuasive.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 8-10, 14, 22 & 25 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for decreasing graft rejection following transplantation, or for activating dendritic cells to polarize naïve T cells into Th2 Helper cells comprising administering an effective amount of structurally and functionally characterized natriuretic peptides of SEQ ID NOs: 1-8, does not reasonably provide enablement for "treating" or preventing (as described on page 11 of the specification) unknown symptoms related to multiple sclerosis or graft rejection using structurally undefined natriuretic peptides. The specification does not enable any person

skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims, for the reasons made of record in Paper No: 20090817, and as follows.

Applicants argue on pages 8-10 of the response that "the specification enables the full scope of these [amended] claims". In contrast to Applicants' assertions, only amended claim 22 is directed to dendritic cell polarization. More importantly, the claims still recite "treating a Th1-mediated immune disease/regulating the Th1/Th2 balance in the immune system…" with structurally and functionally uncharacterized compounds, which therefore, remain not enabled for the reasons made of record in the previous Office action, consistent the teachings of Rudinger previously made of record, because not a single claim recites any structural and functional limitations to enable use of the biologically functional equivalents of ANP or BNP claimed (i.e., based upon the open-ended disclosure recited on page 12, etc. for what constitutes natriuretic peptides (e.g., "examples" and "and the like")).

As previously made of record, the state of the art is well illustrated within the instant specification on pages 5 & 7 & 8, where it is stated that:

> "However, no clinically applicable pharmaceutical preparation has been developed that enables selective inhibition of Th1-mediated immunity and reduction of side effects".

Further, it remains noted that no specific Th-1 mediated immune disease condition involving dysfunction of natriuretic peptide is known in the art or disclosed in the instant specification, whose dysfunction is characterized by altered expression of ANP or BNP, at the time of filing Applicants' invention

Lastly, the claims are not commensurate in scope with the limited guidance provided within the instant specification concerning what biologically functional equivalent ANP or BNP

compounds are required for use in these methods, because, as it relates to the compounds required to practice the currently claimed methods, it was held in *Ex parte Maizel* (27 USPQ2d 1662 at 1665) that:

> Appellants have not chosen to claim the DNA [product] by what it is but, rather, by what it does, i.e., encoding either a protein exhibiting certain characteristics, *or* a biologically functional equivalent thereof. Appellants' claims might be analogized to a single means claim of the type disparaged by the Court of Customs and Patent Appeals in *In re Hyatt,* 708F.2d 712, 218 USPQ 195 (Fed. Cir. 1983). The problem with the phrase "biologically functional equivalent thereof" is that it covers any conceivable means, i.e., cell or DNA, which achieves the stated biological result while the specification discloses, at most, only a specific DNA [product] segment known to the inventor. Clearly the disclosure is *not commensurate in scope with the claim*s [emphasis added].

Thus, in that no structure and little functional language (i.e., ANP, BNP) are recited in the claims, the claims encompass using any "biologically functional equivalent" product, which the court held as not enabled, and because any random modification or mutation to even the peptides of SEQ ID NO: 1 or 4, etc. could be made which retains the desired function of the instant invention, because any such random modification/ mutation manifested within even the defined ANP or BNP compounds of SEQ ID NOs: 1 or 4 required to practice the currently claimed method would be predicted to adversely affect the three-dimensional conformation of the "substance", without requiring undue experimentation to determine otherwise.

Therefore, because it cannot be successfully extrapolated from the limited guidance provided within the instant specification whether the skilled artisan has successfully practiced Applicant's invention, it would require undue experimentation for the skilled artisan to know how to make and use the instant invention, as currently claimed, in light of the unpredictable state of the art in treating immune-related disease states, such as multiple sclerosis or graft rejection; and especially as it relates to use of biologically functional equivalent molecules.

Note MPEP 2164.08 makes clear that "all questions of enablement are evaluated against the claimed subject matter. The focus of the examination is whether everything within the scope of the claim is enabled."

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Stucker, can be reached on (571) 272-0911. The fax phone number for this Group is (571) 273-8300.

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/Robert C. Hayes/, Ph.D.
Primary Examiner, Art Unit 1649
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